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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,796	11/28/2006	Chang Shin Park	20745-002US1 OPA9603-204	3557
26161	7590	02/13/2008	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			BLAND, LAYLA D	
			ART UNIT	PAPER NUMBER
			1623	
			MAIL DATE	DELIVERY MODE
			02/13/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,796	<b>Applicant(s)</b> PARK ET AL.	
	<b>Examiner</b> Layla Bland	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application is a national stage entry of International Application No. PCT/KR04/02653, filed October 15, 2004 and claims foreign priority to Korean Application No. 10-2003-00717777, filed October 15, 2003. The copy of certified copy of the priority has been filed with the instant Application. It is noted that Korean Application No. 10-2003-00717777 is in Korean; no translation of said application into English has been provided.

Claims 1-8 are pending in this application and are examined on the merits herein.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "improving the condition of synovial cells." This phrase is not defined in the specification and it unclear what is intended by this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Watanabe et al. (US 5,650,433, June 22, 1997).

Watanabe et al. teach that flavonoids including apigenin [columns 3 and 4, Table 1; column 6, line 17; column 7, Example 2; claim 4] protect cartilage and are effective for the treatment of arthropathy such as rheumatoid arthritis and osteoarthritis [see abstract and claim 6]. The chondroprotective agent may be in the form of any conventional formulation, including granules [column 7, Example 2] and can be mixed with any pharmaceutically acceptable carriers or diluents [column 5, lines 14-19]. Oral administration is in the range of 0.1 to 500 mg/kg per day [column 5, lines 28-33].

The intended use of a composition, such as “for regenerating cartilage” or “for osteoarthritis” does not impart patentability to a known composition. Effects of reducing joint synovial fluid volume, etc. and regenerating cartilage are inherent properties of the composition. Although Watanabe et al. do not disclose the concentration of apigenin in articular cartilage or synovial fluid, the dosage taught by Watanabe et al. falls within the typical oral dosage recited on page 27 of the instant specification. Thus, the claims are anticipated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (US 5,650,433, June 22, 1997) in view of Niebes et al. (4,268,517, May 19, 1981).

Watanabe et al. teach as set forth above.

Watanabe et al. do not teach ointments or injectables containing apigenin.

Niebes et al. teach a pharmaceutical composition for treating degenerative diseases of the articular cartilage, such as rheumatoid arthritis, containing (+)-catechin [see abstract]. Catechin is a natural product flavonoid [column 1, lines 42-58] with a similar structure to apigenin. Catechin should be administered at daily doses of 1-4g orally or 5-50 mg intraarticularly [column 1, lines 33-36]. If topically administered, the recommended dosage is about 100 mg -2g for each application [column 3, lines 51-56].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare an ointment comprising 1-100 mg of apigenin or an injectable comprising 0.1-10 mg apigenin. Watanabe et al. teach that apigenin may be administered in any conventional formulation for the treatment of rheumatoid arthritis or osteoarthritis and Niebes et al. teach topical and injectable formulations of catechin for the treatment of disorders such as rheumatoid arthritis. Apigenin and catechin have similar structures, are both flavonoids, and are both taught for the treatment of the same disorders, so the skilled artisan would predict that the dosages and formulations taught for catechin would also be effective for apigenin.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/  
Examiner, Art Unit 1623

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623